REMARKS/ARGUMENTS

Claims 40-47 are currently pending in the application. Applicants have amended claim 40. Support for these amendments can be found, for example, at paragraphs [0047] and [0270] of the instant specification. No new matter has been added.

Claim Objections

Applicants acknowledge that claims 43 and 47 stand objected to for depending from a rejected base claim, but would otherwise be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

The Examiner objected to claim 40 for misspelling "actinic keratosis". Applicants have amended claim 40 and submit that this objection is overcome.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 40 under 35 U.S.C. § 112, second paragraph for indefiniteness. The Examiner argued that reciting "cancer and premalignant conditions" makes it unclear whether these conditions are limited to those of the skin. Applicants respectfully disagree, but to facilitate prosecution, have amended claim 40 to clarify this phrase to recite "skin cancers and pre-malignant conditions of the skin." Applicants submit that claim 40 is definite and respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claim 40 under 35 U.S.C. § 102(b) for allegedly being anticipated by the teachings of Gottfried *et al.* GB 2023001 A (1979) ("Gottfried"). The Examiner alleged that Gottfried teaches pharmaceutical compositions for the treatment of cancer with carbenoxolone. Applicants respectfully traverse.

Applicants amended claim 40, as explained above to limit the claim to "skin cancers and pre-malignant conditions of the skin." Gottfried does not teach this limitation of claim 40 and thus cannot anticipate it. Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claim 40-42 and 44-46 for allegedly being obvious over 35 USC § 103 over the teachings of Burchardt. The Examiner alleged that the meaning of the term "pharmaceutically acceptable excipient" as recited in the claims properly encompasses an LTD_4 receptor antagonist as described in Burchardt *et al.* WO 97/15298 ("Burchardt"). Applicants respectfully disagree.

LTD_4 receptor antagonists are used for the treatment of inflammatory disorders, particularly allergic asthma.[1/] Burchardt teaches that LTD_4 receptor antagonists are small molecule antagonists with a generic formula found at page 5 of Burchardt. According to the teachings of Burchardt, when LTD_4 receptor antagonists are combined with glucocorticosteroids they create a synergistic anti-inflammatory effect.[2/] Burchardt also teaches that carbenoxolone is a glucocorticosteroid.[3/]

In their response to Office action filed on January 7, 2010, Applicants submitted references from the art that explain the definition of "pharmaceutically acceptable excipient" by one ordinary skill in the art would exclude an LTD_4 receptor antagonist in this context. [4/] Remington: The Science and Practice of Pharmacy p. 741-742 (2006) ("Remington"), previously included as Exhibit A teaches that excipients are needed, "to stabilize the API (active pharmaceutical ingredient) by providing antioxidant, heavy-metal chelating, or light protection properties. They also may be used to enhance bioavailability and to control the release from dosage forms." About.com defines pharmaceutical excipients as "pharmaceutical additives, the inactive ingredients used to make up a medication. They include dyes, flavors, binders, emollients, fillers, lubricants, preservatives, and many more classifications. Common excipients include cornstarch, lactose, talc, magnesium stearate, sucrose, gelatin, calcium stearate, silicon dioxide, shellac and glaze."[5/] Pharmaceutical-technology.com defines pharmaceutical excipient as, "an inert substance, which is added to a drug to provide bulk, *e.g.* in tablets."[6/] The definition

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1/ *See* Burkhardt at page 1, lines 23-24.
2/ *Id.* at page 1, lines 25-28.
3/ *Id.* at page 2, line 7.
4/ *See* Response filed on January 7, 2010 at page 6.
5/ Web page as found on the Internet at http://bipolar.about.com/od/medications/g/gl_excipient.htm previously included as Exhibit B.
6/ Web page as found on the Internet at http://www.pharmaceutical-technology.com/glossary/excipient.html previously included as Exhibit C.

of excipient in Pifferi and Restani, Il Farmico 58 (2003) 541-550 ("Pifferi"),[7] is as an inert substance added to a prescription to confer a suitable consistency.[8]

The Examiner interpreted the definitions provided by Applicants to encompass the use of a LTD_4 receptor antagonist as a pharmaceutically acceptable excipient.[9] The Examiner argued that a "pharmaceutically acceptable excipient" has activity, but it has less activity than the active agent.[10] The Examiner further argued that the definitions provided by Applicants provide open ended examples of excipients and thus LTD_4 receptor antagonists should be encompassed by these definitions.[11] Further that any requirements for excipients made by the definitions are satisfied by LTD_4 receptor antagonists.[12]

Applicants asserted that one of ordinary skill in the art would define a pharmaceutically acceptable excipient as inert or inactive. The Examiner argued that, "the term 'inactive' is a relative term to define the level of 'activity' of the excipient and, thus, the description of the excipient as an 'inactive' ingredient appears to be a description of the activity of the ingredient as compared to, e.g., the API [active pharmaceutical ingredient] in the medicament." The Examiner went on to argue that, "[b]ecause the carbenoxolone compound and the LTD_4 receptor antagonist each function with a distinct mechanism of action (i.e., a glucocorticosteroid versus a LTD_4 receptor antagonist), the LTD_4 receptor antagonist would also be considered 'inactive' relative to a glucocorticosteroid because it lacks any functionality as a glucocorticosteroid, absent factual evidence to the contrary, and, therefore, also be an excipient as claimed."[13]

Applicants submit that the Examiner has not supported this definition of "activity" with any evidence that it is accepted by one of ordinary skill in the art. The Examiner's rationale amounts to improper use of official notice. "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known."[14]

7/ Previously included as Exhibit D.
8/ *See* Pifferi at 541.
9/ *See* the Office Action at pages 7-11.
10/ *Id.* at page 8, lines 11-20 and from page 9, line 17 to the bottom of page 10.
11/ *Id.* pages 7-8, bridging paragraph and first seven lines of the second paragraph of page 8.
12/ *Id.* page 9, first full paragraph.
13/ *See* the Office action from page 8, line 21 to page 9, line 2.
14/ *See* MPEP § 2144.03(A).

Applicants submit that the Examiner's definition for "activity" is not an art accepted definition. For example, acetaminophen and codeine are paired in one dosage unit for pain relief. These two drugs act through different molecular pathways to relieve pain. However, the FDA describes both substances as active ingredients.[15/] Similarly, Burchardt teaches that LTD_4 receptor antagonists are combined with glucocorticosteroids to create a synergistic anti-inflammatory effect.[16/] Thus, Burchardt teaches that glucocorticosteroids and LTD_4 receptor antagonists are active in the same way, i.e. their anti-inflammatory effect. Thus, if "active" is seen in the context of the activity of the API, here carbenoxolone, a LTD_4 receptor antagonist would have to be deemed an active agent as well, and thus not a pharmaceutically acceptable excipient.

The Examiner also cited Exhibit B as teaching an excipient must 1) be safe in the amount used with the drug, 2) not affect bioavailability and 3) be manufactured in accordance with good standards.[17/] The Examiner argued that a LTD_4 receptor antagonist would meet these criteria, and so should be deemed a pharmaceutically effective excipient. Applicants respectfully disagree.

Applicants submit that while these properties are necessary for excipients, they are not sufficient. Excipients are used for specific reasons, e.g. as dyes, flavors, binders, emollients, fillers, lubricants and/or preservatives.[18/] This is further demonstrated by the teachings of Pifferi. The Examiner argued that Pifferi argued that pharmaceutically acceptable excipients are not inert, but instead should fill numerous and important functions.[19/] Pifferi still distinguishes between active ingredients and excipients[20/] but presents various functions for excipients including for guaranteeing the stability, precision and accuracy of the dose of active agent.[21/] Pifferi also teaches that excipients are diluents, bulking agents, disintegrants, lubricants, coloring agents, and/or sweeteners.[22/] Pifferi also teaches that excipients are used to enhance compliance,

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15/ *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=ACETAMINOPHEN%20AND%20CODEINE%20PHOSPHATE, collected on the Internet on October 18, 2010, submitted, herewith as Exhibit E.

16/ Burchardt at page 1, lines 25-28.

17/ *See* the Office action at page 9, first full paragraph.

18/ *See* Exhibit B.

19/ *See* the Office action at page 9, line 21.

20/ *See* Pifferi at *e.g.* Figure 1.

21/ *Id.* at page 542, left column, first paragraph.

22/ *Id.* at page 542, bridging paragraph between the columns.

dose precision and accuracy, stability, manufacturability, desaggregation, dissolution, controlled release and absorption.[23/]

Thus, Applicants submit that it is not sufficient to say that a substance is pharmaceutically acceptable in order to be deemed an excipient. The excipient must also have some function appropriate to being an excipient. The Examiner has not presented that an LTD_4 receptor antagonist would have any of the functions mentioned in the Exhibits that were previously submitted. The Examiner has only argued that these examples are not exhaustive. However, the Examiner has also not provided evidence that a LTD_4 receptor antagonist would have any function appropriate to a pharmaceutically acceptable excipient. Indeed, the Examiner is unable to provide any reason why one of ordinary skill in the art would use a LTD_4 receptor antagonist as an excipient.

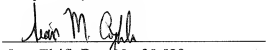
For all of the above reasons, Applicants submit that Burchardt does not teach or suggest the methods of claims 40-42 and 44-46 and respectfully request that this rejection be withdrawn.

23/ *Id.* at page 542, Table 1.

CONCLUSION

Applicants respectfully request prompt examination in the application. If there are any questions regarding this Response, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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Overview

Drug Name	**ACETAMINOPHEN AND CODEINE PHOSPHATE**
Active Ingredient(s)	**• ACETAMINOPHEN; CODEINE PHOSPHATE**
Form(s) and Strength(s) Available	**• CAPSULE; ORAL: 300MG; 15MG ; 300MG; 30MG ; 300MG; 60MG • SOLUTION; ORAL: 120MG/5ML; 12MG/5ML • TABLET; ORAL: 300MG; 15MG ; 300MG; 30MG ; 300MG; 60MG ; 325MG; 15MG ; 325MG; 30MG ; 325MG; 45MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** ; 500MG; 15MG ; 500MG; 30MG ; 500MG; 60MG ; 650MG; 30MG ; 650MG; 60MG**

Details about drugs are organized by FDA Application Number (NDA or ANDA or BLA).

Click on a drug name or application number to view drug details:
Click on a column header to re-sort the table:

Drug Name and FDA Application Number	Dosage Form/Route	Strength	Marketing Status	Company
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040098)	SOLUTION; ORAL	120MG/5ML; 12MG/5ML	Discontinued	CLONMEL
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040119)	SOLUTION; ORAL	120MG/5ML; 12MG/5ML	Prescription	HI TECH PHARMA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040223)	TABLET; ORAL	Multiple Strengths	Prescription	DURAMED PHARMS BARR
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040419)	TABLET; ORAL	Multiple Strengths	Prescription	MALLINCKRODT
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040443)	TABLET; ORAL	Multiple Strengths	Prescription	WATSON LABS FLORIDA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040452)	TABLET; ORAL	300MG; 30MG	Discontinued	ABLE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040459)	TABLET; ORAL	300MG; 60MG	Discontinued	ABLE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 040779)	TABLET; ORAL	300MG; 30MG	Prescription	AMNEAL PHARMS NY
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 081249)	TABLET; ORAL	300MG; 60MG	Discontinued	SANDOZ
ACETAMINOPHEN AND CODEINE PHOSPHATE	TABLET; ORAL	300MG; 30MG	Discontinued	SANDOZ

(ANDA # 081250)				
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 083871)	TABLET; ORAL	300MG; 15MG	Discontinued	HALSEY
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 083872)	TABLET; ORAL	300MG; 30MG	Discontinued	HALSEY
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 084360)	TABLET; ORAL	300MG; 30MG	Discontinued	WHITEWORTH TOWN PLSN
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 084656)	TABLET; ORAL	300MG; 30MG	Discontinued	ROXANE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 084659)	TABLET; ORAL	300MG; 15MG	Discontinued	ROXANE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 084667)	TABLET; ORAL	300MG; 60MG	Discontinued	ROXANE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085217)	TABLET; ORAL	325MG; 30MG	Discontinued	EVERYLIFE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085218)	TABLET; ORAL	300MG; 30MG	Discontinued	WARNER CHILCOTT
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085288)	TABLET; ORAL	300MG; 30MG	Discontinued	KV PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085291)	TABLET; ORAL	300MG; 30MG	Discontinued	SANDOZ
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085363)	TABLET; ORAL	325MG; 45MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	Discontinued	KV PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085364)	TABLET; ORAL	325MG; 15MG	Discontinued	KV PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085365)	TABLET; ORAL	300MG; 60MG	Discontinued	KV PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085607)	TABLET; ORAL	300MG; 60MG	Discontinued	WHITEWORTH TOWN PLSN
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085676)	TABLET; ORAL	300MG; 30MG	Discontinued	VITARINE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085794)	TABLET; ORAL	300MG; 30MG	Discontinued	MUTUAL PHARM
ACETAMINOPHEN AND	TABLET; ORAL	300MG; 15MG	Discontinued	MUTUAL

CODEINE PHOSPHATE (ANDA # 085795)				PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085861)	SOLUTION; ORAL	120MG/5ML; 12MG/5ML	Prescription	ACTAVIS MID ATLANTIC
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085868)	TABLET; ORAL	300MG; 30MG	Prescription	RANBAXY
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085896)	TABLET; ORAL	300MG; 30MG	Discontinued	VALEANT PHARM INTL
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085917)	TABLET; ORAL	300MG; 30MG	Discontinued	SANDOZ
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085964)	TABLET; ORAL	300MG; 60MG	Discontinued	SANDOZ
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 085992)	TABLET; ORAL	300MG; 15MG	Discontinued	WARNER CHILCOTT
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 086366)	SOLUTION; ORAL	120MG/5ML; 12MG/5ML	Discontinued	ROXANE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 086549)	TABLET; ORAL	300MG; 60MG	Discontinued	HALSEY
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 086681)	TABLET; ORAL	300MG; 30MG	Discontinued	PUREPAC PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 086683)	TABLET; ORAL	300MG; 60MG	Discontinued	PUREPAC PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087006)	SOLUTION; ORAL	120MG/5ML; 12MG/5ML	Prescription	WOCKHARDT
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087083)	TABLET; ORAL	300MG; 60MG	Prescription	RANBAXY
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087141)	TABLET; ORAL	300MG; 30MG	Discontinued	LEDERLE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087275)	TABLET; ORAL	300MG; 60MG	Discontinued	WATSON LABS
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087276)	TABLET; ORAL	300MG; 30MG	Discontinued	WATSON LABS
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087277)	TABLET; ORAL	300MG; 15MG	Discontinued	WATSON LABS
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087306)	TABLET; ORAL	300MG; 60MG	Discontinued	WARNER CHILCOTT
ACETAMINOPHEN AND CODEINE PHOSPHATE	TABLET; ORAL	300MG; 60MG	Discontinued	SANDOZ

(ANDA # 087423)				
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087433)	TABLET; ORAL	300MG; 15MG	Discontinued	SANDOZ
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087508)	SOLUTION; ORAL	120MG/5ML; 12MG/5ML	Prescription	PHARM ASSOC
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087653)	TABLET; ORAL	300MG; 60MG	Discontinued	MUTUAL PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087762)	TABLET; ORAL	300MG; 30MG	Discontinued	PURACAP PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087919)	TABLET; ORAL	300MG; 30MG	Discontinued	USL PHARMA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 087920)	TABLET; ORAL	300MG; 60MG	Discontinued	USL PHARMA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088324)	CAPSULE; ORAL	300MG; 30MG	Discontinued	TEVA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088353)	TABLET; ORAL	300MG; 15MG	Discontinued	DURAMED PHARMS BARR
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088354)	TABLET; ORAL	300MG; 30MG	Discontinued	DURAMED PHARMS BARR
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088355)	TABLET; ORAL	300MG; 60MG	Discontinued	DURAMED PHARMS BARR
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088537)	CAPSULE; ORAL	300MG; 15MG	Discontinued	TEVA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088599)	CAPSULE; ORAL	300MG; 60MG	Discontinued	TEVA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088627)	TABLET; ORAL	300MG; 15MG	Prescription	TEVA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088628)	TABLET; ORAL	300MG; 30MG	Prescription	TEVA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 088629)	TABLET; ORAL	300MG; 60MG	Prescription	TEVA
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089080)	TABLET; ORAL	300MG; 30MG	Discontinued	PUREPAC PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089183)	TABLET; ORAL	300MG; 15MG	Discontinued	SUPERPHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089184)	TABLET; ORAL	300MG; 30MG	Discontinued	SUPERPHARM

ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089185)	TABLET; ORAL	300MG; 60MG	Discontinued	SUPERPHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089231)	TABLET; ORAL	650MG; 30MG	Prescription	MIKART
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089238)	TABLET; ORAL	300MG; 30MG	Prescription	MIKART
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089244)	TABLET; ORAL	300MG; 60MG	Discontinued	MIKART
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089253)	TABLET; ORAL	300MG; 30MG	Discontinued	SUPERPHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089254)	TABLET; ORAL	300MG; 60MG	Discontinued	SUPERPHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089363)	TABLET; ORAL	650MG; 60MG	Prescription	MIKART
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089450)	SOLUTION; ORAL	120MG/5ML; 12MG/5ML	Prescription	MIKART
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089478)	TABLET; ORAL	300MG; 15MG	Discontinued	AM THERAP
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089479)	TABLET; ORAL	300MG; 30MG	Discontinued	AM THERAP
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089480)	TABLET; ORAL	300MG; 60MG	Discontinued	AM THERAP
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089481)	TABLET; ORAL	300MG; 15MG	Discontinued	AM THERAP
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089482)	TABLET; ORAL	300MG; 30MG	Discontinued	AM THERAP
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089483)	TABLET; ORAL	300MG; 60MG	Discontinued	AM THERAP
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089511)	TABLET; ORAL	500MG; 15MG	Discontinued	ROXANE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089512)	TABLET; ORAL	500MG; 30MG	Discontinued	ROXANE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089513)	TABLET; ORAL	500MG; 60MG	Discontinued	ROXANE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089671)	TABLET; ORAL	300MG; 15MG	Discontinued	MUTUAL PHARM
ACETAMINOPHEN AND	TABLET; ORAL	300MG; 30MG	Discontinued	MUTUAL

CODEINE PHOSPHATE (ANDA # 089672)				PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089673)	TABLET; ORAL	300MG; 60MG	Discontinued	MUTUAL PHARM
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089805)	TABLET; ORAL	300MG; 30MG	Prescription	VINTAGE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089828)	TABLET; ORAL	300MG; 60MG	Prescription	VINTAGE PHARMS
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089990)	TABLET; ORAL	300MG; 15MG	Prescription	VINTAGE
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089997)	TABLET; ORAL	300MG; 15MG	Prescription	WATSON LABS
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089998)	TABLET; ORAL	300MG; 30MG	Prescription	WATSON LABS
ACETAMINOPHEN AND CODEINE PHOSPHATE (ANDA # 089999)	TABLET; ORAL	300MG; 60MG	Prescription	WATSON LABS

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